Translation

PCT/JP2004/006139

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference KW0123	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/JP2004/006139	International filing date (*day/month/year*) 28 April 2004 (28.04.2004)	Priority date (*day/month/year*) 29 April 2003 (29.04.2003)
International Patent Classification (IPC) or national classification and IPC A61K 47/04, 31/50		
Applicant KOWA CO., LTD.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

   a. ☐ *(sent to the applicant and to the International Bureau)* a total of _____ sheets, as follows:

      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

   ☒ Box No. I Basis of the report
   ☐ Box No. II Priority
   ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   ☐ Box No. IV Lack of unity of invention
   ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   ☐ Box No. VI Certain documents cited
   ☐ Box No. VII Certain defects in the international application
   ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
18 October 2004 (18.10.2004)	11 March 2005 (11.03.2005)
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/JP2004/006139

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:

☐ international search (under Rules 12.3 and 23.1(b))

☐ publication of the international application (under Rule 12.4)

☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ The international application as originally filed/furnished

☐ the description:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the claims:

pages _____, as originally filed/furnished

pages* _____, as amended (together with any statement) under Article 19

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the drawings:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
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Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-20	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-20	NO
Industrial applicability (IA)	Claims	1-20	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

<Documents cited in the international search report>

Document 1: David D. Hile et al., Active growth delivery from poly (D,L-lactide-co-glycolide) foams prepared in supercritical CO2, Journal of Controlled Release, 2000, Vol. 66, p. 177-185

Document 2: Petra Sencar-Bozic et al., Improvement of nifedipine dissolution characteristics using supercritical CO_2, International Journal of Pharmaceutics, 1997, Vol. 148, p. 123-130

Document 3: JP 2002-345940 A (Zaidan Hojin Kagawa Sangyo Shien Zaidan), December 3, 2002

Document 4: JP 61-227520 A (Daiichi Pharmaceutical Co., Ltd., Watanabe Yakuhin Kogyo Kabushiki Kaisha), October 9, 1986

Document 5: JP 6-040714 A (Shionogi & Co., Ltd.), February 15, 1994

Document 6: JP 2000-198776 A (Kowa Company, Ltd.), July 18, 2000

<Commentary>

Based on the descriptions in documents 1-6 cited in the international search report, the inventions of claims 1-20 lack an inventive step.

Document 1 states that a foam obtained by treatment of a porous polylactide-glycolide copolymer and growth factor with supercritical CO_2 has excellent release from the growth factor. Document 2 states that nifedipine dissolution is improved by treatment of PEG4000 and poorly soluble nifedipine with supercritical CO_2.

As described in document 3, it is possible to produce a controlled release material in which the controlled release ingredient is carried in the pores of a porous material by bringing an organic polymer material such as wood or plastic, or an inorganic material such as ceramic or glass in contact with a starting material containing the controlled release ingredient and a supercritical or subcritical liquid. Moreover, as described in documents 3-5, a silica porous body is generally used as a carrier for drugs, etc.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of Box V:

Furthermore, in the field of pharmaceutics, persons skilled in the art suitably select and determine the base material and the drug to be used, the types of additives, the content ratio of the ingredients, and the manufacturing method, etc., in accordance with the objective. This examination finds that persons skilled in the art can easily prepare the inventions of claims 1-20 by including a drug that is very poorly soluble in water (such as the drugs described in document 6) as the drug in a pharmaceutical preparation with excellent solubility obtained by treatment of porous polylactide-glycolide copolymer or PEG4000 described in documents 1 and 2 and the drug with supercritical CO_2 liquid, and additionally by using a silica porous body having the specific properties described in claims 1-7 as the base material, and specifying the content ratio of the ingredients and the manufacturing method.